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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/086,286	03/01/2002	Robert D. Torgerson	D0188/7135	3327

7590 01/29/2007  
Elizabeth R. Plumer  
Wolf, Greenfield & Sacks, P.C.  
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Boston, MA 02210

EXAMINER
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BUI, VY Q

ART UNIT	PAPER NUMBER
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3734

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/29/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

# Office Action Summary

Application No.

10/086,286

Applicant(s)

TORGERSON ET AL.

Examiner

Vy Q. Bui

Art Unit

3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-10 and 12-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-10 and 12-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-3, 5-10, 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over CRUZ, Jr-(4,148,664) in view of MECHANIC (5,332,475).

As to claims' 1-3, 6-10 and 13-14, Cruz-'664 (col. 4, lines 50-62; col. 6, lines 26-34; Table 1) discloses a fibrous collagen hemostatic product having a bulk density in a range of 1.5-3.7 lbs/ft<sup>3</sup> required for a hemostatic product, and a neutral (pH=7) or acidic (pH<7) or alkaline (pH>7) treatment solution for an un-denatured collagen. Cruz-'664 (col. 6, lines 26-34) also discloses avoiding denaturalization of the collagen. Cruz-'664 does not disclose explicitly using water as a treatment as a treatment solution for suspending collagen fibrils as recited in the claim. However, Mechanic-'475 (col. 2, lines 42-68; col. 3, ll. 1-2; col. 4, ll. 19-53) discloses using collagen fibrils or finely ground bovine skin collagen in a cross-linking process not subjected to an acid dissolution to make collagen fiber/fabric/matrix to be used inside a human being as an implant. Inherently, the product to be used inside a human body must have been sterilized. Specially, MECHANIC (col. 4, lines 54-64; claim 2, lines 1-8) discloses proteinaceous material/collagen fibril(s) being suspended in an aqueous media such as water (having a pH of from about 6.8 to 8.6) to avoid denaturalization of the collagen. Mechanic-'475 explicitly

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teaches avoiding denaturalization of collagen fibrils (col. 4, lines 19-50) by suspending collagen fibrils in water (col. 4, lines 50-64). It would have been obvious to one of ordinary skill in the art at the time of the invention to use water as a treatment solution for a hemostatic product as disclosed by Cruz-'664 in view of Mechanic-'475, as using water would minimize denaturalization of the collagen fibrils.

As to claims 5 and 12, Cruz-'664 and Mechanic-'475 disclose a hemostatic collagen product having substantially all limitations in the claims except for a hemostatic agent. It is well known to incorporate a hemostatic agent to a collagen product such as a fabric/matrix/pad to enhance hemostatic effect. It would have been obvious to one of ordinary skill in the art to incorporate a hemostatic agent to MECHANIC collagen product so as to enhance the hemostatic effect of the MECHANIC collagen product.

### ***Response to Arguments***

Applicant's arguments filed 11/6/2006 have been fully considered but they are not persuasive. The affidavit affirms that the solution of the present invention has a pH number from 3.04 to 3.09. However, it is not clear if the applicants have any disclosure or support for this feature in the original disclosure at the time the application was filed.


### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vy Q. Bui whose telephone number is 571-272-4692. The examiner can normally be reached on Monday-Tuesday and Thursday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on 571-272-4959. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
01/22/07

Vy Q. Bui  
Primary Examiner  
Art Unit 3734